

Claims 2,3,7,13,21 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 2 and 3, "the target entity" lacks antecedent basis after the term's omission from claim 1. Recitations in claims 7,13,21 and 25 (2 occurrences) of "preferably" , render portions of the respective claims indefinite and ambiguous.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5,7,13 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gauch et al PGPUBS Document US 2005/0244882, having an effective filing date of 3/28/2000. Gauch et al disclose method of concentrating or isolating and purifying liquid samples from contaminants (paragraphs 12 and 43-50) comprising contacting sample with aqueous buffer solutions and washing solutions (paragraphs 136-138) and then contacting the solutions with a superabsorptive material 12/13/14, which upon the contacting is more effective to efficiently remove or sorb the solution(s) than the nucleic acid, thus isolating the nucleic acid and other target entities (paragraphs 146-148...178,179). The superabsorptive material comprises a composite in that it contains sponge sorbing layer 13, superabsorptive layer 14, and if necessary, membrane layer 12.

For dependent claims 2,3,5 and claim 33, Gauch also disclose removal of lower molecular weight decomposition products or contaminants and their being dissolved in the buffer solutions (paragraph 136, paragraph 43 also suggesting solvent extraction of both target entities and dissolvend contaminants). The solvents comprise water for claim 7 (paragraph 178 disclose water removal) and single or double-strand DNA for claim 13 (paragraph 12).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(e) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauch et al PGPUBS Document US 2005/0244882, having an effective filing date of 3/28/2000, in view of Eschwey et al patent 4,902,559. Claim 8 differs by requiring the superabsorbent materials to be swollen as the target entity is separated from solution. Eschwey teaches at column 1, lines 7-16, column 4, lines 1-24 that the ability to freely swell without restriction is a property of superabsorbent materials for a variety of applications, such property increasing the capacity for liquid retention.

Claims 15-26,28,29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauch et al PGPUBS Document US 2005/0244882, having an effective filing date of 3/28/2000, in view of Eschwey et al patent 4,902,559 in combination with Yao et al PGPUBS US 2002/0193030 and Fan PGPUBS US 2004/0029166. These claims differ by requiring the superabsorbing material to comprise polymer containing vinylic monomers and anionic, cationic and/or zwitterionic monomers such as surfactants. Eschwey further teaches such vinylic monomers, polymers and copolymers including acrylic acid monomers (column 3, lines 57-67) as does Yao et al for superabsorbent composite copolymers for laboratory, including nucleic acid sample collection and analysis (paragraphs 9,18-20,44 and 45) as does Fan (paragraphs 33...49-52). Yao also teach inclusion of charged or neutralized (zwitterionic) sorbent fibers (paragraphs 74-77). In summary, it would have been obvious to one of ordinary skill in the arts of assaying nucleic acid-containing samples to have utilized the superabsorbent polymers taught by Eschwey, Yao and Fan, so as to effectively sorb and bind the variety of biological and chemical contaminants having differing charges that may be present, in addition to effectively binding the nucleic acids, until addition of selective elution solvent.

Acrylic acid and other acrylic and acrylate monomers and polymer constituents of copolymers for claims 16-22 which may be cross-linked or ionizable are further discussed at column 3, lines 55-68 of Eschwey; paragraphs 74-78 of Yao and paragraphs 49-50 of Fan. For claim 23, Eschwey teaches at column 1, lines 7-16, column 4, lines 1-24 that the ability to freely swell without restriction is a property of superabsorbent materials for a variety of applications, such property increasing the capacity for liquid retention. Fan teaches various size particles of the superabsorbent, thus powdery or bead-like material at paragraphs 46-48 for claims 24 and 25. Gauch discloses claim 26, since layer 14 can be considered a coating of layer 23, as well as the container (isolator 10) of claims 28 and 29.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bloch patent 5,856,192 also disclose forms of superabsorbent polymers utilized to isolate single or double-stranded DNA or RNA in chromatographic devices.

Applicant's arguments with respect to claims 1,33 and claims dependent therefrom, have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment, especially concerning the superabsorbent polymer or composite as effective upon contacting, to more efficiently sorb the solvent than the nucleic acid so as to concentrate the sample, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication, or requests for telephonic or personal interviews with the examiner, should be directed to Joseph Drodge at his direct government telephone number of 571-272-1140. The examiner can normally be reached on Monday-Friday from approximately 8:00 AM to 1:00PM and 2:30 PM to 5:30 PM.

Alternatively, to contact the examiner, send a communication via E-mail communication to the Examiner's Patent Office E-mail address: "Joseph.Drodge@uspto.gov". Such E-mail communication should be in accordance with provisions of MPEP (Manual of Patent Examination Procedures) section 502.03 & related MPEP sections. E-mail communication must begin with a statement authorizing the E-mail communication and acknowledging that such communication is not secure and will be made of record, under Patent Internet Usage Policy Article 5. A suggested format for such authorization is as follows: "Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file.

Additionally, the examiner's supervisor, Duane Smith, of Technology Center Unit 1797, can be reached at 571-272-1166.

The formal facsimile phone number, for official, formal communications, for the examining group where this application is assigned is 571-273-8300. The facsimile phone number for informal communication directly with the examiner is 571-273-1140.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD
4/5/2010
/Joseph W. Drodge/
Primary Examiner, Art Unit 1797